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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,415

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Yasuomi Urano

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10/28/2008

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EXAMINER

ROYDS, LESLIE A

ART UNIT

PAPER NUMBER

1614

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DELIVERY MODE

10/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,415	Applicant(s) URANO ET AL.	
	Examiner Leslie A. Royds	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 10-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>26 June 06; 02 Nov 06; 18 Dec 06; 05 Dec 07; 01</u> | 6) <input type="checkbox"/> Other: _____ |

May 08

DETAILED ACTION

Claims 1-23 are presented for examination.

Acknowledgement is made of the present application as a proper National Stage (371) application of PCT Application No. PCT/JP04/19628, filed December 28, 2004.

Applicant's Information Disclosure Statements (IDS) filed June 26, 2006 (one page); November 2, 2006 (one page); December 18, 2006 (two pages); December 5, 2007 (one page); and May 1, 2008 (two pages) have each been received and entered into the present application. As reflected by the attached, completed copies of form PTO/SB/08(A-B) (seven pages total), the Examiner has considered the cited references, with the exception of Cite No. 9 to Yamazaki on the IDS filed June 26, 2006, which does not contain a date of publication and, thus, fails to comply with the requirements of MPEP §609. The reference has been placed in the application file, but the information referred to therein has not been considered. Applicant is advised that the date of any re-submission of any item of information contained in this IDS or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 C.F.R. 1.97(e). See MPEP §609.05(a).

Applicant's response filed December 5, 2007 to the requirement for restriction/election dated November 5, 2007 has been received and entered into the present application. Pursuant to the notice dated February 25, 2008, the response filed December 5, 2007 was non-compliant. Applicant's response filed March 11, 2008 correcting the deficiencies described in the notice dated February 25, 2008 was also received and entered into the present application. Pursuant to the new requirement for restriction/election dated June 4, 2008, the requirement for restriction/election dated November 5, 2008 was vacated in lieu of the requirement dated June 4, 2008. Applicant's response filed July 7, 2008 to the requirement for restriction/election dated June 4, 2008 has been received and entered into the present application.

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Requirement for Restriction/Election

Applicant's election without traverse of the invention of Group II (claims 5-9), directed to a method of inhibiting the formation of an active complex of γ -secretase using a cholesterol synthesis inhibitor or a protein geranylgeranylation regulator, and the election of species of HMG-CoA reductase inhibitors as the cholesterol synthesis inhibitor and the species of pitavastatin as the specific species of HMG-CoA reductase inhibitor, for examination on the merits, in the reply filed July 7 2008, is acknowledged by the Examiner.

Therefore, for the reasons above and those made of record at pages 2-8 of the previous Office Action dated July 7, 2008, the requirement remains proper and is hereby made **FINAL**.

Claims 1-4 and 10-23 are withdrawn from examination pursuant to 37 C.F.R. 1.142(b) as being directed to non-elected subject matter.

The claims corresponding to the elected subject matter are claims 5-9 and such claims are herein acted on the merits.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 5 is directed to a method of inhibiting the formation of an active complex of γ -secretase using a cholesterol synthesis inhibitor or a protein geranylgeranylation regulator, wherein the cholesterol synthesis inhibitor is pitavastatin.

In particular, instant claim 5 provides for the use of pitavastatin, but fails to specifically set forth the exact procedural steps that must be performed in order to achieve the objective instantly claimed. As

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a result, the claims fail to clearly, deliberately and precisely set forth exactly what method or process Applicant is intending to encompass by the instant claims. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Accordingly, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the scope of the subject matter for which Applicant is presently seeking protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Allison et al. (WO 02/15892; 2002).

Allison et al. teaches a method for the prevention, delay of progression or treatment of a disease and disorder that may be inhibited by the enhancement of insulin secretion, the inhibition of an ACE inhibitor and/or by the inhibition of HMG-CoA reductase comprising administering to a warm-blooded animal, including man, in need thereof jointly therapeutically effective amounts of at least two therapeutic agents selected from the group consisting of (a) an insulin secretion enhancer or a pharmaceutically acceptable salt thereof and (b) at least one of the active ingredients selected from the group consisting of (i) HMG-CoA reductase inhibitors, such as, *inter alia*, pitavastatin (p.3, l.17-22) or a pharmaceutically acceptable salt thereof; and (ii) ACE inhibitors or a pharmaceutically acceptable salt thereof (p.10, l.15-25).

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Regarding Applicant's objective of inhibiting the formation of an active complex of γ -secretase (claim 5) or the inhibition of the formation of an active complex of γ -secretase in lipid rafts (claim 6), the pitavastatin compound disclosed by Allison et al. is identical to the compound presently recited (and elected) in Applicant's instant claims and is "used" in the same manner (note that Applicant's claims are non-specific to exactly how the compound is "used"; see rejection *supra* under 35 U.S.C. 112, second paragraph) as that instantly claimed. Therefore, the method of use disclosed by Allison et al. must necessarily possess the same function in inhibiting the formation of an active complex of γ -secretase (as in instant claim 5) or inhibiting the formation of an active complex of γ -secretase in lipid rafts (as in instant claim 6) as that instantly claimed whether recognized by the patentee or not because products of identical chemical composition cannot have mutually exclusive properties when used in exactly the same manner. In other words, if the prior art teaches the identical chemical and/or physical structure of the claimed compound and further teaches the identical manner of using the same, the properties that Applicant discloses and/or claims are necessarily present. Please see MPEP §2112.

It is again noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation, the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of

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the prior invention”).

Conclusion

Rejection of claims 5-9 is proper.

Claims 1-4 and 10-23 are **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

October 22, 2008

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/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614